|  | ed States Paten | t and Trademark Office | UNITED STATES DEPAR<br>United States Patent and<br>Address: COMMISSIONER F<br>P.O. Box 1450<br>Alexandria, Virginia 22:<br>www.uspto.gov | OR PATENTS       |
|--|-----------------|------------------------|--|------------------|
| APPLICATION NO.                                | FILING DATE     | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
| 10/764,118                                     | 01/23/2004      | William N. Washburn    | LA0108 NP  | 7884             |
| 23914 7:                                       | 590 09/15/2006  |                        | EXAM   | IINER            |
| LOUIS J. WILLE                                 |                 |                        | SHAMEEM, GOLAM M   |                  |
| BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT |                 |                        | ART UNIT   | PAPER NUMBER     |
| P O BOX 4000<br>PRINCETON, NJ 08543-4000       |                 |                        | 1626   |                  |
|  |                 |                        | DATE MAILED: 09/15/2006  |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|  | Application No.   | Applicant(s)                 |  |  |  |  |
|--|---|------------------------------|--|--|--|--|
|  | 10/764,118  | WASHBURN ET AL.              |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                     |  |  |  |  |
|  | Golam M. M. Shameem, Ph.D.  | 1626                         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |                              |  |  |  |  |
| <ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> |   |                              |  |  |  |  |
| Status   |   |                              |  |  |  |  |
| 1) Responsive to communication(s) filed on $24 J_{c}$  | <u>ıly</u> 2006.  |                              |  |  |  |  |
|  | action is non-final.  |                              |  |  |  |  |
| 3) Since this application is in condition for allowar  |   |                              |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                              |  |  |  |  |
| Disposition of Claims  |   |                              |  |  |  |  |
| 4) Claim(s) <u>1-24</u> is/are pending in the application.   |   |                              |  |  |  |  |
| 4a) Of the above claim(s) <u>11-24</u> is/are withdrawn from consideration.  |   |                              |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                              |  |  |  |  |
| 6)⊠ Claim(s) <u>1-10</u> is/are rejected.  |   |                              |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                              |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.   |                              |  |  |  |  |
| Application Papers   |   |                              |  |  |  |  |
| 9) The specification is objected to by the Examine   | r.  |                              |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acc   |   | Examiner.                    |  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). |                              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                              |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                              |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |                              |  |  |  |  |
| a) All b) Some * c) None of:   |   |                              |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |                              |  |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No.</li> </ul>  |   |                              |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in Application No   |   |                              |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                              |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                              |  |  |  |  |
|  |   |                              |  |  |  |  |
|  |   |                              |  |  |  |  |
|  |   |                              |  |  |  |  |
|  |   |                              |  |  |  |  |
| 1)       Notice of References Cited (PTO-892)       4)       Interview Summary (PTO-413)         2)       Notice of Draftsperson's Patent Drawing Review (PTO-948)       Paper No(s)/Mail Date.  |   |                              |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   | 5) 📃 Notice of Informal F   | Patent Application (PTO-152) |  |  |  |  |
| Paper No(s)/Mail Date 12/07/2004. /5/2.6/69         6)         Other:  |   |                              |  |  |  |  |

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## **DETAILED ACTION**

#### **Priority**

This application claims benefit for domestic priority under 35 U.S.C. § 119(e) [to a provisional application 60/442,659 01/24/2003], is acknowledged.

#### Status of Claims

Claims 1-24 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on July 24, 2006 and that has been entered.

Claims 11-24 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 12/07/2004 and 05/26/2004, which has been entered in the file.

## **Response to Election/Restriction**

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-10 drawn to compounds and compositions, and the elected species as set forth found in Example 1 on page 44 of the specification with traverse is acknowledged. The traversal is on the ground(s) that the nonelected pending claims 11-24 should be rejoined and examined with the elected Group I because "Applicants do not believe that a serious burden would be imposed upon the Examiner to search the Applicants' claims" (Remarks page 1) and therefore, a search and examination of the entire Markush group should be made without a serious burden.

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Applicant's arguments are fully considered and found unpersuasive at this time because the Invention groups I-V differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. The invention groups I-V are related to a set of structurally diverse and dissimilar compounds, compositions and their methods of uses (chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly), which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Because of many classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the Examiner. Nevertheless, the Examiner may reconsider to rejoin method of use claims commensurate in scope with the product claims when the case would be found in condition for allowance [provided those method claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-11 of co-pending Application No. 10/763,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The compounds taught by co-pending applications are similar to instant application because a reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since Washburn *et al* teach the <u>generic</u> compounds and compositions which are similar to the instantly claimed invention.

The subject matter claimed in the instant application is fully disclosed and covered in copending Application No. 10/763,878. Therefore, the disclosure of Washburn *et al* that teach many permutation and combination substitutions (including various Markush variable substitutions, such as  $R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ ,  $R_{11}$  and X etc), which would easily place Applicants invention in possession of the public at the time of Applicants invention was filed. The

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indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). Therefore, in the instant case, one skilled in the chemical art would be motivated to choose to replace various Markush variables in core formula I to obtain the desired products in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Moreover, any other differences are but obvious structural modifications, which would be apparent to one skilled in the chemical art that can use similar substitutions, would expect to have the same or essentially the same results. Therefore, in looking at the instant claimed compounds as a whole, the claimed compounds would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

## **Telephone Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (571)-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft

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documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M M Shameem, Ph.D. Primary Examiner Art Unit 1626 Technology Center 1600

OLAM M. M. SHAMEEM, PH.D PRIMARY EXAMINER

July 31, 2006